

## PATENT APPLICATION

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Swan <i>et al.</i>	Examiner:	Naff, David M.
Serial No.:	10/723,505	Group Art Unit:	1657
Filed:	November 26, 2003		
For:	BIOCOMPATIBLE POLYMERIZATION ACCELERATORS	Docket No.:	SRM0006/US

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

CERTIFY THAT ON 8 FEB 2010, THIS PAPER IS BEING  
ELECTRONICALLY TRANSMITTED TO THE UNITED STATES PATENT  
AND TRADEMARK OFFICE VIA THE OFFICE'S EFS-WEB.

  
PAUL L. WEAVER

DECLARATION UNDER 37 C.F.R. § 1.131

Dear Sir:

Dale G. Swan and Ronald F. Ofstead declare the following

1. They are applicants of the above-identified patent application.
2. The invention claimed in the above-identified application was conceived and reduced to practice in the United States of America prior to October, 2002, as indicated by the following facts, supported by attached Exhibits 1-14.
3. All of the work described in Exhibits 1-13 relative to the above-identified application was performed at SurModics, Eden Prairie, Minnesota, U.S.A., prior to October 2002.
4. Exhibits 1-13 include proposals, synthetic schemes, and experimental data describing the preparation of polymerization accelerators having biocompatible functional groups, and the use of these accelerators for preparing biocompatible polymeric matrices, which can be formed in the presence of tissue or cells. The accelerators described in these Exhibits include ones having an N-vinyl amide functionality and a sulfonate functionality.

5. Exhibits 1 and 2 consist of pages 20 and 26, respectively, notebook #2683 which were dated and signed prior to October 2002, and which describe a scheme for the synthesis of the biocompatible polymerization accelerator N-vinylsuccinimide-2-sulfonate (NVSS). NVSS has N-vinyl amide and sulfonate functionalities and is specifically described in the above-identified patent application at pages 29-30 (Example 4, compound 4). NVSS falls under the scope of the accelerator recited in claims of the patent application.

6. Exhibits 3-10 consist of notebook pages 21, 26, 27, 30, 31, 37, 39, and 39 (cont.) respectively, from notebook #2706 which were dated and signed prior to October 2002, and which describe the details of the laboratory synthesis of NVSS.

7. Exhibit 11 consists of page 30 from notebook #2683 which was dated and signed prior to October 2002, and which describe a scheme for the synthesis of the biocompatible polymerization accelerator potassium 3-(3-[formyl(vinyl)amino]propanoyl)oxy)propane-1-sulfonate (NVF-SPA), as well as the details of its laboratory synthesis. NVF-SPA has N-vinyl amide and sulfonate functionalities and is specifically described in the above-identified patent application at page 30 (Example 5, compound 5). NVF-SPA falls under the scope of the accelerator recited in claims of the patent application.

8. Exhibit 12 consists of a SurModics Intellectual Property and Proprietary Product Idea Form (the SurModics IP Form) that was dated and signed prior to October 2002. The SurModics IP Form describes the synthesis of biocompatible polymerization accelerators, including ones having N-vinyl amide and sulfonate functionalities. The SurModics IP Form also describes the use of biocompatible polymerization accelerators for preparing protective hydrogel coatings around cells.

9. Exhibit 13 consists of page 79 from a notebook which was dated and signed prior to October 2002, which describes compositions that include the polymerizable material hyaluronic acid macromer and the polymerization accelerator

NVSS. This composition falls under the scope of the composition recited in claims of the patent application, and is described in the above-identified patent application at page 32 (Example 9). The composition was polymerized to form a biocompatible polymeric matrix, which can also be formed in the presence of tissue or cells.

10. Exhibit 14 consists of U.S. Patent No. 6,669,994 (issued Dec. 30, 2003) including Dale G. Swan as an inventor. The application leading to the '994 patent (U.S. 09/840,406) was filed in the U.S. Patent Office on April 23, 2001, and was pending in the U.S. Patent Office prior to October 2002, during which the invention claimed in the above-identified application was conceived and reduced to practice.

The 09/840,406 patent application shows that prior to October 2002, Dale G. Swan had contemplated sulfonate, phosphonate, and carboxylate groups as biocompatible functional groups. Column 13, lines 40-43, of the 09/840,406 patent application states, "Examples of suitable charged groups include salts of organic acids (e.g., sulfonate, phosphonate, and carboxylate groups), as well as combinations thereof." Column 13, lines 40-43, states, "Additionally, such charged groups provide a combination of such desirable characteristics as antithrombogenicity and hemocompatibility."

Therefore, the 09/840,406 application shows that Dale G. Swan had possession of the claimed invention prior to October 2002 because, as evidenced by 09/840,406, it was obvious to Dale G. Swan to include phosphonate and carboxylate along with sulfonate as biocompatible functional groups.

11. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements have been made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or patent issuing thereon.

Date

Nov. 29, 2010

Dale G. Swan

Dale G. Swan

Applicant: Swan et al.  
Serial No.: 10/723,505  
File: November 26, 2003  
For: BIOCOMPATIBLE POLYMERIZATION ACCELERATORS

Examiner: Naff, David M.  
Group Art Unit: 1657  
Docket No.: SRM0006/US

12/1/2010  
Date

Ronald F. Ofstead  
Ronald F. Ofstead

#61089v1